National
Grain and Feed
Association

North American
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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 02N-0278
Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The National Grain and Feed Association (NGFA) and the North American Export Grain Association (NAEGA) submit this joint statement in response to the Food and Drug Administration's notice of proposed rulemaking that would require U.S. purchasers, U.S. importers or their agents to submit to FDA prior notice of the importation of food into the United States, effective December 12, 2003. The FDA-proposed regulations are intended to implement portions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 [Bioterrorism Act].

The NGFA, established in 1896, consists of 1,000 member companies from all sectors of the grain, feed, processing and exporting business that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. The NGFA's membership includes country, terminal and export elevators; feed manufacturers; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries. The NGFA also consists of 36 affiliated state and regional grain and feed associations, as well as two international affiliated associations. The NGFA also has established strategic alliances with the Pet Food Institute and the Grain Elevator and Processing Society.

NAEGA, established in 1912, is comprised of private and publicly owned companies and farmer-owned cooperatives involved in and providing services to the bulk grain and oilseed exporting industry. NAEGA member companies ship practically all of the bulk grains and oilseeds exported each year from the United States. The Association's mission is to promote and sustain the development of commercial export of grain and oilseed trade from the United States. NAEGA acts to accomplish this mission from its office in Washington D.C., and in markets throughout the world. NAEGA's principal interest in this rulemaking pertains to the troubling precedents that would be established that would very likely be replicated by other countries and applied against U.S. exports of bulk commodities.

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The NGFA and NAEGA are committed to enhancing the security of U.S. agricultural facilities and support reasonable, prudent steps that enable FDA to better respond promptly and effectively to a threatened or actual terrorist attack on the U.S. food or feed supply, without imposing undue burdens or costs on the food and feed system. As a demonstration of this commitment, the NGFA on November 16, 2001 published an ***Agribusiness Facility and Operations Security*** guide that outlines security issues and considerations that may need to be addressed at agribusinesses. The guide includes sections on conducting a facility vulnerability assessment; improving the general security of the physical facility and grounds; implementing prudent security operating, shipping and receiving procedures; and a sample emergency action plan. The guide has been distributed widely by the NGFA, and is available at no charge to members and nonmembers alike.

The NGFA and NAEGA join with other sectors of the food and feed chain in believing that substantial sections of FDA's proposed prior notification rules exceed the requirements of the Bioterrorism Act, transcend what is needed to facilitate effective inspection of imported food by the agency at U.S. ports of entry, and would not materially contribute to improvements in the safety or security of the U.S. food supply. Further, several of FDA's proposed regulations are burdensome or unworkable; would cause major disruptions and higher costs for a U.S. food system whose efficiency is the envy of the world; likely would make the United States vulnerable to challenges for erecting non-tariff barriers to trade at the World Trade Organization; and would set a troubling precedent that might be replicated by other countries against U.S. agricultural exports. **We cannot stress this latter point too hard. FDA's final rules very likely will become the template for practices that could be adopted by foreign countries and applied with equal force and vigor against U.S. exports of bulk and processed agricultural commodities, feed and feed ingredients, meat products and other agricultural exports. We strongly encourage FDA to weigh carefully the negative impact its regulations for prior notice may have on international commerce.** To facilitate trade, we also believe it is essential that FDA staff U.S. ports of entry on a 24-hour, seven-day-a-week basis.

For these and other reasons, the NGFA and NAEGA strongly urge FDA to make major modifications to its proposed prior notification rules. Particularly troubling are FDA's proposals concerning the extensive amount of information required in prior notices; the deadlines for providing prior notice, particularly regarding the estimated arrival times and specific ports of entry for cross-border trade with Canada and Mexico; restrictions imposed on information that can be amended in prior notices in advance of shipment arrival; and the vague language concerning the obligation and potential liability of importers to ascertain the identity and locations of growers of imported food articles.

We offer the following comments concerning specific sections of FDA's proposed rules for submitting prior notice to the agency under the Bioterrorism Act:

- **Section 1.277 – Definitions Applicable to Prior Notice:** In the narrative preceding its proposed regulations, FDA requests comments on whether the definition of "country from which the article of food was shipped" should include "intermediate destinations." The NGFA and NAEGA do not believe FDA should require prior notices to contain the names of countries that comprise intermediate destinations. In many instances, an imported food article may pass through a number of ports or stops in a variety of countries and never be unloaded. Further, the U.S. importer in most cases has no control or knowledge of which ports or stops a vessel or other conveyances may make en route to the U.S. port of entry. To require importers to discover and report "intermediate destinations" would be unreasonable, burdensome and costly, and would not measurably improve U.S. food safety or security.

- **Section 1.278 – Consequences of Failing to Submit Adequate Prior Notice:** FDA proposes that imported food articles for which prior notice is not received or for which such notice is "inadequate (e.g., untimely, inaccurate or incomplete) shall be refused admission" into the United States. The Bioterrorism Act itself expressly states, in relevant part, that an "article of food imported or offered for import **without submission of such (prior) notice**...shall be refused admission into the United States." *[Emphasis added.]* Therefore, the NGFA and NAEGA recommend that the agency clarify in its final regulations that "inadequate" prior notice is confined to material omissions or major errors that are of such gravity as to seriously impede the agency's ability to review and appropriately respond to the notice (e.g., by making a determination to assign inspectors to a port of entry to monitor the inbound shipment of food articles). We believe this recommended change is consistent with the previously cited statutory language found in the Bioterrorism Act, and is further warranted by another provision of the Act *[Section 307(2)(B)(ii)]* that states FDA "**shall** determine whether there is...any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals" when making a determination of whether to hold a food article at the port or removal to a secure facility. *[Emphasis added.]*

  To reflect the statute, the NGFA and NAEGA recommend that this section of the proposed regulations be revised as follows. *[New language boldfaced and underscored; deleted language stricken through]*:

  "Section 1.278(a): If an article of food is imported or offered for import with no prior notice or inadequate ***prior notice*** *(i.e.,* ~~*untimely, inaccurate, or incomplete)*~~ ***material omissions or major errors that are of such gravity as to impede the agency's ability to receive, review or appropriately respond to the notice***) ~~*prior notice*~~*, the food shall be refused admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1).* ***When making such a determination, FDA shall determine if there is credible evidence or information indicating that such article of food presents a threat of serious adverse health consequences or death to humans or animals.***"

- **Section 1.285 – Parties Authorized to Submit Prior Notice:** FDA's proposal unnecessarily limits the number of entities authorized to submit prior notice concerning the import of food articles into the United States.

  Specifically, FDA proposes to allow prior notice to be submitted **only** by the U.S. purchaser or importer of an article of food – or the agent acting on behalf of the U.S. purchaser or importer – who resides or maintains a place of business in the United States. FDA's proposed rule also makes these parties responsible for the completeness and accuracy of the information provided in the prior notice [Section 1.288], as well as for executing any amendments to such notices under Sections 1.289, 1.290 and 1.294 of the agency's proposed regulations. In so doing, FDA is operating under the generalization that "in most circumstances, information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States." *[**Federal Register**, Feb. 3, 2003, page 5433.]*

  The Bioterrorism Act is silent as to the entity required to submit prior notice. The NGFA and NAEGA respectfully recommend that the purchaser/importer or its U.S. agent frequently is not in the best position to provide the most accurate or timely information related to import shipments. It is our understanding that foreign facilities already notify the U.S. Customs Service concerning the contents and anticipated arrival times of food articles being presented for import into the United States. Similarly, U.S. livestock and poultry producers who purchase products from Canadian feed manufacturers are not in a position to provide prior notification to FDA because it is the foreign facility – not the U.S. grower – who knows the final contents and approximate quantity of the import shipment. For rail shipments, it is the carrier that controls the shipment routing and arrival. In the case of U.S.-Canada trade, it is our understanding that Canadian rail carriers already transmit electronic manifests and provide anticipated arrival times to the U.S. Customs Service under the Smart Border Program. For vessel shipments, once the product is loaded and the bill of lading is issued, the responsibility for the cargo transfers to the vessel owner. For these reasons, we recommend that FDA change its proposed regulations to specifically authorize foreign facilities registered with FDA under Section 415 of the Bioterrorism Act, as well as transporters or their agents, to submit prior notices or amendments thereto.

  We also strongly urge FDA to develop a seamless method that enables the U.S. Customs Service to provide such prior notification and subsequent amendments directly to FDA for the purposes of meeting the agency's obligations under the Bioterrorism Act. We also believe FDA, in concert with the U.S. Customs Service, should evaluate and incorporate into its final rules the effectiveness of existing bilateral Customs agreements – such as C-TPAT, FAST and the previously alluded to SMART Border Plan – that already address the risks associated with bioterrorism.

- **Section 1.286 – Deadline for Submitting Prior Notice:** FDA proposes to require that prior notice be submitted by no later than noon of the calendar day before the day the article of food is scheduled to arrive at the U.S. port of entry or border-crossing point. The Bioterrorism Act mandates that prior notification occur within five days of arrival of the food article at the port of entry. We are cognizant that the "default" provision of the Bioterrorism Act would have required that prior notice be received no fewer than eight hours before a shipment's arrival. But nonetheless, the NGFA and NAEGA believe that FDA's proposed regulation requiring that prior notice be submitted by noon of the day before a food article is presented for import into the United States is unreasonable, particularly for: 1) certain transportation modes, such as cross-border rail and truck shipments from Canada and Mexico; and 2) companies that rely on the efficiencies of just-in-time deliveries. We also believe this prior notice deadline is unreasonable when considered in the context of what we believe to be overly stringent limits proposed by FDA concerning the type of information that can be updated through amendments to prior notices in Sections 1.289, 1.290 and 1.293 of its proposed regulations, which we address later. For original prior notices, we recommend that FDA consider allowing notices to be submitted as early as five days, or as late as two to four hours, prior to anticipated arrival at U.S. ports of entry.

- **Section 1.287 – Procedures for Submitting Prior Notice:** The NGFA and NAEGA commend FDA for providing for the electronic transmission of prior notices. Consistent with Section 1.231 of its proposed regulations pertaining to the registration of domestic and foreign facilities under the Bioterrorism Act, we urge FDA to incorporate language into this section stating that a fee will not be charged for submitting prior notices in either electronic, fax or paper format. We also urge FDA to provide a safe harbor for compliance in the event its electronic submission system is not operating. We do not believe it is practical for FDA to propose to require the submission of the printed version of the prior notice form or amendments via fax, e-mail or in person at FDA field offices.

- **Section 1.288 – Information Required in Prior Notices:** FDA proposes to require the submission of an extensive – and we believe unnecessary – amount of information in prior notices that far exceeds the statutory requirements. The Bioterrorism Act mandates that the information to be provided in prior notices is to include the identity of: 1) the article (of food); 2) the manufacturer and shipper; 3) the grower of the food article, if known within the specified time period within which the prior notice is required; 4) the country from which the food article originates and was shipped; and 5) the anticipated port of entry for the food article.

  Yet FDA proposes to add to this statutory list such additional mandatory information as: 1) the name and contact information for the individual submitting the prior notice; 2) the entry type and U.S. Customs ACS entry number or other U.S. Customs identification number associated with the

import; 3) the location where the article is being held if prior notice either was not received or was deemed inadequate by the agency; 4) the complete FDA product code for the food article; 5) the common or usual name or market name of the food article; 6) the trade or brand name, if different from the common, usual or market name; 7) the quantity, described from the smallest package size to the largest container; 8) the lot or code numbers or other identifiers of the food, if applicable; 9) the anticipated arrival information and time that the imported food article is expected to reach the U.S. port of entry; 10) the name of the port of entry where the imported food article is expected to arrive; and 11) the name and contact information for each of the following – the importer, the owner and the consignee related to the shipment.

By any measure, these requirements are excessive and are far beyond the information FDA reasonably needs to perform its duties with respect to imports under the Bioterrorism Act. Further, we are concerned that the volume of information FDA proposes to collect would overwhelm the agency, and perhaps make it less – rather than more – effective in allocating its inspection resources. The NGFA and NAEGA particularly object – and urge FDA to delete or revise – the following proposed required information:

- The entry type and U.S. Customs ACS entry number or other U.S. Customs identification number associated with the import. Frequently, this information is not known at the time prior notification would be required by FDA.

- The type of food article. We believe that information required by FDA concerning the type of food article should be simplified to consist of the common or usual name or market name, rather than also requiring the complete FDA product code or trade/brand name, which may not be known to the foreign exporter. This also would alleviate the unnecessary complexity, burden and costs associated with reporting specific subclasses or species of foods, feed or feed ingredients – and the associated quantities of each – that would be required under the agency's current proposal.

- The quantity, described from the smallest package size to the largest container. For bulk commodities and commingled lots, particularly those delivered in multi-car train and vessel shipments, this requirement is both inappropriate and unnecessary. Instead, we recommend that those submitting prior notices for bulk commodity shipments be allowed to report the "approximate quantity" of the food article contained in the entire import shipment, rather than by individual rail cars or cargo holds.

- The lot or code numbers or other identifiers of the food, if applicable. We encourage FDA to clarify that for commodities or feed ingredients imported in bulk, it is inappropriate to require lot or code numbers of individual lots comprising the commingled mass.

- The name and contact information of the importer, owner and consignee. We suggest that FDA require information be provided only on the entity submitting the prior notice, which could be either the importer, owner or consignee, but not all three.

The NGFA and NAEGA have particular – and major – concern over FDA's proposal pertaining to the identification of growers and growing locations of imported food articles. FDA proposes to require the "name, address, phone number, fax number and e-mail address of all growers and the growing location if different from the business address, if known at the time" the prior notice is submitted. As noted previously, the Bioterrorism Act states that the prior notice is to contain the identity of the "grower of the (food) article ***if known*** within the specified time that notice is required to be provided." *[Emphasis added.]* The NGFA and NAEGA urge FDA to clarify in its final regulations that grower-related information is required to be submitted **only if such information becomes available and known as a matter of due course** to the party submitting the prior notice. FDA should neither require nor imply that the importer or other party submitting the prior notice has a responsibility or obligation to solicit, determine or otherwise obtain information on the identity of specific foreign growers of food articles imported into the United States. To do otherwise would be burdensome, costly and unrealistic for the party providing prior notice.

Further, we believe it is important for FDA to clarify the applicability of this provision to bulk commodity imports. Bulk commodities are sourced from numerous farms and elevators, and commingled prior to and during loading and shipment. Thus, any comprehensive list of growers of bulk commodities or ingredients in a commingled mass produced by multiple growers is largely meaningless, and would be of negligible value to FDA for purposes under the Bioterrorism Act. In the case of bulk and commingled commodities, it should be sufficient for FDA to be able to trace the shipment back to its point of origination – the manufacturer or foreign facility [whose identity is required under Section 1.288(f)] and the shipper [whose identity is required in Section 1.288(i)] of the proposed regulations.

Further, these FDA-proposed requirements run the very real risk of subjecting the United States to a challenge before the World Trade Organization for erecting non-tariff trade barriers through *de facto* disruptions to food articles unless the foreign grower's identity is known. Or, equally or even more troubling, as noted in our initial comments, it could lead to the imposition of similar requirements by foreign countries importing U.S. agricultural commodities, with dire consequences for U.S. agricultural exports.

- **Section 1.289 – Amendments to Prior Notices:** FDA proposes to severely restrict the type of information that submitters of prior notices could convey via amendments to those notices to reflect new or updated information prior to arrival of the imported food article at the U.S. port of entry. Specifically,

FDA proposes to permit amendments to prior notices only for changes involving: 1) product identity information that could not be provided at the time the original prior notice was submitted. However, even in this instance, FDA proposes not to allow changes in the general identity of the food article, citing an example that a product previously identified as "refrigerated fresh cod" and "refrigerated fresh salmon" could not be changed to "refrigerated fresh cod" and "canned shrimp"; 2) the identity of the grower, if it becomes known; and 3) the anticipated arrival time of the import shipment. For other changes, FDA proposes to require that the original prior notice be canceled and an entirely new one be submitted, which would have the effect of delaying either the arrival or release of the import shipment at the U.S. port of entry by at least an extra day. Further, FDA proposes to allow only one amendment to an existing prior notice; any additional amendments would require the cancellation of the existing prior notice and the submission of a new one.

The NGFA and NAEGA believe FDA's proposal concerning amendments to prior notices is far too stringent and confining. As noted previously, we also believe FDA should provide for prior notification or amendments to be submitted by rail carriers, vessel owners and other transporters or their agents, which are in a much better position than the U.S. purchaser or importer to know about the status of a shipment's estimated arrival time and port of entry. We also strongly urge the agency to provide more flexibility in allowing the updating of relevant information through amendments to prior notices, without requiring the issuance of an entirely new notice. For instance, we believe submitters should be allowed to amend prior notices to reflect **changes in the approximate quantity** of the shipment, to facilitate the common practice of "topping off" shipments with a like kind of food article. Further, for cross-border imports from Canada and Mexico, we believe FDA should allow amendments to prior notices to reflect **changes in the border crossing points** resulting from traffic congestion or other conditions. Since FDA already will have received prior notice containing such information as the type of food article, the originating country, and the name of the manufacturer and shipper, we believe the agency has sufficient information to make a determination as to whether the articles in the shipment pose a potential risk to the safety or security of the U.S. food supply.

- **Section 1.290 – Product Identity Amendments to Prior Notices:** In this section, FDA proposes to require that those submitting prior notices provide the grower identity if known at the time they submit a product identity amendment. The NGFA and NAEGA reiterate our previous comments that FDA should clarify again in this section – as well as in subsequent Section 1.294(b) – that the identity and contact information of the grower is required **only if such information becomes available and known as a matter of due course** to the entity submitting the prior notice amendment.

- **Section 1.291 – Deadline for Submitting Amendments to Prior Notices:** As noted previously, the NGFA and NAEGA recommend that FDA expand the type of information contained in prior notices that is allowed to be updated through amendments prior to the arrival of the import shipment. We believe the FDA-proposed requirement that such amendments be submitted no later than two hours prior to the time of arrival is appropriate for this additional information, as well as for information pertaining to changes in the product identity.

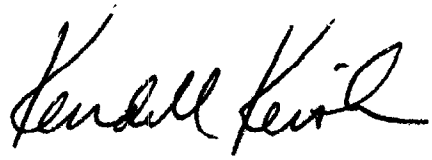
- **Section 1.293 – Consequences for Failure to Submit Product Identity Amendments:** FDA proposes that if the submitter of a prior notice has informed the agency that he/she would be submitting an amendment to the product identity, but subsequently fails to do so, the original prior notice would be deemed null-and-void. We believe this is unreasonable, and should be deleted.

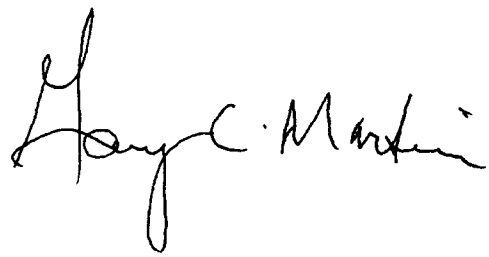
- **Section 1.294 – Changes in Anticipated Arrival Time of Import Shipments:** FDA proposes to require that amendments containing updated information be submitted to the agency if the anticipated port of entry changes or if the scheduled arrival time is more than three hours later or one hour earlier than prescribed on the original prior notice form. The NGFA and NAEGA believe this requirement is not feasible for some transport modes, particularly cross-border rail and truck shipments of food articles from Canada or Mexico, whose arrival times frequently are unpredictable. We encourage FDA to consider whether the major ports of entry for food-related imports from Canada and Mexico are well known, and whether the agency cannot already preposition an adequate number of inspectors at such border locations to meet anticipated needs. This would help obviate the need for submitting amendments updating the anticipated arrival times for cross-border imports. Alternatively, FDA should require that changes in the anticipated arrival time should be submitted to the agency by the transporter itself, which would be in the best position to provide accurate, updated information.

In closing, the NGFA and NAEGA appreciate this opportunity to provide our collective input on FDA's proposed regulations to implement the prior notification requirements of the Bioterrorism Act. We believe our proposed changes will contribute to implementing the law in the most efficient manner possible, while minimizing the regulatory burdens and costs that could disrupt efficient import operations by companies engaged in providing an abundant and affordable food supply to U.S. and world consumers.

We pledge our continued proactive efforts to work with our industry sectors and with government to further enhance the safety and security of the nation's food and feed supply.

Sincerely,





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